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EXHIBIT II

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II

DATE: DEC - 3 1986

SUBJECT: Initial Review of Trial Burn Plan for Eli Lilly

FROM: Fred Haber, Quality Assurance Specialist
Monitoring Management Branch

TO: John Brogard, P.E.
Hazardous Waste Facilities Branch

I have reviewed the above stated plan, specifically regarding the adequacy of its waste analysis plan (Section C of revised Part B Application) and waste feed and scrubber water analyses contained in the Entropy proposal. Inadequacies are detailed below.

1. Unless Section C clearly details why the generated wastes could not contain the three Appendix VIII compounds more difficult to incinerate than carbon tetrachloride (i.e., trichlorofluoromethane, tribromomethane, dichlorodifluoromethane) at levels greater than 100 ppm, the applicant must provide analytical data for these parameters.

   Any analytical data provided must accurately represent the subject wastes. Sampling strategies, methodologies and equipment used to obtain representative data must be detailed. Both individual waste heterogeneity and variations in composition resulting from different production compaigns must be explained, and considered fully in the design of sampling strategies, methodologies, and choice of equipment.

2. Referencing series of methods, as is done in Table C-5 of Section C, is insufficient. Each parameter analyzed must be matched to a specific method, including method of sample preparation. If modified, EPA methods are being used, the modifications must be detailed. If the modification is considered by us to be significant, precision and accuracy data will need to be submitted.

   Detection limits and their method of determination must be included, and the detection limit provided for any given sample must take into account any dilution resulting from compositing.

3. a. Regarding off-site wastes from other Eli Lily facilities (e.g., from North Carolina and other facilities in Puerto Rico) destined for incineration at Mayaguez, we would like some assurance that the waste characterization process described for wastes generated in Mayaguez also applies to these other facilities. Of particular concern are the procedures for sampling and analyzing Appendix VIII compounds more difficult to incinerate than carbon tetrachloride, if they could be present in the waste.

   b. A related concern involves the screening of off-site wastes destined for incineration at Mayaguez. Page 15 of Section C of the revised Part B application indicates the number of drums sampled in the different size shipments of an individual waste. The plan needs to

explain fully how sampling the number indicated results in an accurate representation of that waste. This should include a discussion of the homogeneity or lack of it between drums and within drums. The randomness of drum selection also should be discussed. Section C also must detail how representative samples of incoming bulk waste are obtained.

Additionally, Section C does not provide any details of sampling equipment and methods. The types of equipment, their materials of construction, and method of use need to be provided.

c. The plan needs to provide the details of the fingerprinting process for incoming wastes to be incinerated at Mayaguez. Specific examples of fingerprinting parameters and their methods of measurement need to be provided.

4. Regarding analyses taking place as part of the trial burn, Table 2-1 on page 11 of the Entropy proposal lists GC/ECD and GC/FID respectively for waste mixture analyses of these parameters. The specific methods of sample preparation and analyses, rather than analytical techniques need to be provided.

Also, it should be noted that EPA apparently does not have any recommended methods, which include the use of the above stated detectors, for the analysis of the subject compounds. Consequently, the appropriateness of methods using these detectors would need to be demonstrated by providing certain precision and accuracy data on real environmental samples.

Table 2.1 also references EPA Methods 501.2 and 8010 for analyses of carbon tetrachloride and methylene chloride respectively in scrubber water. Method 8010 is appropriate for analysis of both methylene chloride and carbon tetrachloride. However, for Method 501.2 to be used for the analysis of carbon tetrachloride, the analyst would have to demonstrate the appropriateness of the method by collecting and providing to us certain precision and accuracy data on real environmental samples. Additionally, qualitative confirmation of results by GC/MS would have to be performed if 501.2 is used. We suggest that Method 8010 (SW-846) be considered for this analysis.

Additionally, the specific method of sample preparation needs to be provided for these scrubber water analyses.

Regarding scrubber water analyses, Section 2.1.2 of page five of the Entropy proposal states that three scrubber makeup and three scrubber discharge samples from each run will be mixed to provide one makeup and one discharge sample for POHC analysis. Due to the likelihood of the loss of these volatile POHCs as a result of the mixing of these samples, we feel that any compositing needs to be done in the laboratory in a manner that minimizes the loss of volatiles. This matter needs to be addressed further in the Entropy proposal.

5. No information is provided regarding analysis of incinerator effluent ash. If no ash is produced, a statement needs to be made to such effect. If ash is produced, the analysis of this ash needs to be addressed.

6. Regarding the quality assurance/quality control program for trial burn waste feed and scrubber water analyses described in the Entropy proposal and for general waste characterization sampling and analytical activities described in Section C of the revised Part B application, the information provided is inadequate. It should be noted that simply making a statement, that the quality control specified in referenced methods will be followed, will not be sufficient. In most cases, it is too general. At a minimum, the details of actual practice need to be provided regarding:

   a. QA organization and responsibilities;

   b. the use of inter-laboratory performance evaluation samples and systems audits by external parties;

   c. the use of blanks;

   d. procedures routinely used to assess the precision and accuracy of data e.g., frequency, level, and types of spikes, duplicates (field and lab), duplicate spikes;

   e. data validation and corrective action procedures;

   f. calibration processes (e.g., number of calibration points, calibration checks);

   g. sample containers, preservation, and holding times;

   h. preventive maintenance of instruments;

   i. education, training, and experience of analytical and sampling personnel; and,

   j. all documentation processes, including chain-of-custody procedures.

cc: Wilber Sellers - 2ES-AW

EXIBIT III

TRIAL BURN SCHEDULE

ACTIVITY	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV
• SCRUBBER DESIGN REVISION	XXXXX						
• DRAWING APPROVAL		XXX					
• FOUNDATION PREPARATION			XXX				
• EQUIPMENT INSPECTION				XXX			
• EQUIPMENT DELIVERY					XXX		
• EXISTING EQUIP. RELOC.					XXX		
• SCRUBBER INSTALLATION					XXXXX		
• START UP						XXX	
• OFFICIAL TRIAL BURN							XXX

J. J. RIVERA
5/11/87

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